USDA Foreign Agricultural Service
GAIN Report
Global Agriculture Information Network
Template Version 2.08

Required Report - public distribution

Date: 6/27/2007

GAIN Report Number: HR7003

Croatia

Biotechnology

Agricultural Biotechnology Report

2007

Approved by:
Quintin Gray
U.S. Embassy

Prepared by:
Andreja Misir

Report Highlights:
Croatia is a net food importer and goverment policy is geared toward raising agricultural productivity and, to a lesser extent, limiting imports. EU memebership is also a priority for the Croatian goverment, and new laws and agricultural policies will increasingly morror those of the EU. The Croatian public remains very sceptical about agricultural biotechnology. There has also been a general demonization of U.S. food products as "Frankenstein Foods". In Croatia, several pieces of legislation have been introduces that seek to regulate the import and cultivation of biotechcrops and foods. However, there is a lack of political will to proceed with further legislation that would enable imports of biotech products.

Includes PSD Changes: No
Includes Trade Matrix: No
Annual Report
Vienna [AU1]
[HR]

EXECUTIVE SUMMARY

Croatia is a net food importer and government policy is geared toward raising agricultural productivity and, to a lesser extent, limiting imports. EU membership is also a priority for the Croatian government, and new laws and agricultural policies will increasingly mirror those of the EU.

The Croatian public remains very skeptical about agricultural biotechnology. There has also been a general demonization of U.S. food products as “Frankenstein Foods”.

In 2004, samples of foodstuff and seed taken from the market were randomly tested for biotech traces, which resulted in the withdrawal of some products from the market and penalties because the biotech products were not labeled.

In Croatia, several pieces of legislation have been introduced that seek to regulate the import and cultivation of biotech crops and foods. The laws regulating biotechnology are: Food Act and Law on Genetically Modified Organisms. Another important legal document on biotechnology is the “Ordinance on Levels of GMO in Products Under Which Products that are Placed on the Market Do Not Have to be Labeled as Containing GMO” (with list of biotech products that can be contained in a product in trace amounts).

SECTION II

BIOTECHNOLOGY TRADE AND PRODUCTION

a. In Croatia there are no commercially produced biotech crops
b. In Croatia there are no biotech crops under development.
c. Croatia is not importing biotech crops/products because there are no laws or acts outlining the registration process for biotech crops/products for market release.
d. Croatia is not a food aid recipient.
e. Croatia does not produce any biotech crops developed outside of the United States or any biotechnology crops in general.

SECTION III

BIOTECHNOLOGY POLICY

a. Agricultural biotechnology regulatory framework:

The Food Act governs the possible import, licensing and labeling of any foods/feed containing biotech products. The latest Food Act was approved by Parliament on April 25th, 2007 and published in government gazette number 46 on May 7th, 2007. This law outlines many regulations that would enable biotech products to enter the market and be labeled. However, the regulations have not yet been passed, so the labeling threshold is governed by the Government Ordinance on GMO Levels in Products Under which Products Placed on the Market Do Not Have to be Labeled as Products Containing GMO passed on December 3, 2004 (see section IIIb for additional details). Company penalties for violating the "novel food" provisions of the Food Law concerning placing novel foods on the market or labeling are from Kn 100,000 to Kn 500,000, with responsible individual fined from Kn 5,000 to Kn 10,000.

Law on Genetically Modified Organisms (Law on GMOs) is an overarching law for biotechnology. The Law on Genetically Modified Organisms (Governmental Gazette 70/2005) together with the Food Act (and forthcoming future regulations) regulate the importation,

transshipment, production, usage, and sale of products of agricultural biotechnology (all food, feed, and seed). This Law established a testing and licensing regime that is so restrictive that it constitutes a de facto ban. The highest penalties for breaching the provisions of this Law range from Kn 500,000 to Kn 1,000,000 for the responsible company and from Kn 20,000 to Kn 70,000 for the responsible employee in the company.

i. Responsible Ministries and their Roles:

Ministry of Science (MOS), Education and Sport

- According to the GMO Law the MOS, is responsible for limited-contained use of GMOs.

Ministry of Health and Social Welfare (MOHSW)

- According to the Food Act the MOWSW, is responsible for all the issues regarding food, foodstuff and feed containing biotechnology content.
-
- According to the GMO Law the MOHSW, is the umbrella ministry and coordinating body for all biotechnology issues.

Ministry of Culture (MOC) - Environment Protection Department

- According to the GMO Law the MOC, is responsible for the intentional introduction of GMOs to the environment.

Ministry of Agriculture, Forestry (MOAF) and Water Management

- According to the Food Act Ministry of Agriculture is a Central Body of the Government responsible for food/feed safety, food/feed quality and food/feed hygiene as well as for official inspections. This Ministry is also a contact point for the EU when mentioned issues are concerned. Ministry of Agriculture has joint responsibility with the Ministry of Health for all the issues regarding food, foodstuff and feed containing biotechnology content.

- According to the GMO Law the MOAF has responsibilities for feed and animal food; reproduction material in agriculture, forestry and veterinary medicine; drugs in veterinary medicine and pesticides; is also responsible for giving its consent for the intentional release of biotech products into the environment.

ii. Role and Membership of Biosafety Committee (if any):

The GMO Law requires the establishment of a Council for GMOs with the specific task of assisting Governmental bodies to apply the Law. The Council has 17 members appointed by the Government of Croatia based on nominations from the pertinent Ministries. Council membership lasts for four years. The Council's work is independent and public. According to the Law, the Council's tasks include: tracking gene technology development and usage; tracking scientific breakthroughs and giving opinion and incentives for usage of gene technology and GMOs; giving opinions on social, ethical, technical, scientific and other conditions of GMO use; advising responsible institutions on GMO and gene technology issues; informing the public on GMO and gene technology development and also giving viewpoints and opinions.

The GMO Law also calls for establishing a Board for Limited Usage of GMOs with 11 members made up of scientists from the fields of microbiology, genetics, medicine, biochemistry,

molecular biology, pharmacy, biotechnology, agriculture, forestry, veterinary medicine, nature and environmental protection, and occupational protection. In addition, the GMO Law requires establishing a board for the introduction of biotech products into the environment and consisting of nine scientists from the fields of: genetics, ecology, nature protection, and environment protection, agriculture, forestry, veterinary medicine, biochemistry, molecular biology, microbiology, and medicine. The tasks of these boards include: giving opinions on biotech usage in terms of legal procedures as outlined by the GMO Law, giving opinions and proposals for preparing other legislation on GMO usage, giving opinions and proposals to responsible ministries on biotech usage issues and other expert work as outlined by the GMO Law and related regulations. According to the law, these two boards should report to the GMO Council once a year.

The old and new Food Act/s called/s for the establishment of the Croatian Food Agency, which already began its work in 2004. The Agency work consists of providing scientific and technical support to legislators as well as providing scientific advices in all areas that have direct and indirect influence on food and feed safety. Apart from that the Food Agency is required to work on many other issues concerned with feed, food and nutrition and is a provider of scientific opinion to the Ministry of Health and Ministry of Agriculture when deciding on placing on the market GMO food and/or feed.

iii. Assessment of political factors that may influence regulatory decisions related to agricultural biotechnology:

Although EU membership is a priority for the Croatian government and the country's new laws and agricultural policies will increasingly mirror those of the EU, biotech opponents in Croatia have been emboldened by the perceived success of Austria, Slovenia, and to a certain degree Italy in standing up to the European Commission on biotech approvals. Thus complying with EU regulations has little meaning as long as Croatia positions itself within a regional group of "healthy," GMO-free countries.

At the moment Croatia clearly sees its future as a "niche market for healthy food" (NOTE: In Croatia, the word "healthy" encompasses everything from conventional, organic to non-biotech products), and Croatian officials see little need to implement a procedure to allow biotech seed imports given a lack of agricultural demand for biotech products to combat drought, pests, or soil problems. Government officials acknowledge the legal obligation to open their agricultural market to foreign imports and openly acknowledge that Croatia is positioning itself as a GMO-free, "healthy" tourist destination. Also the Croatian public is generally very negative towards biotech products.

b. Biotechnology crops approved for food, processing and feed:

No biotech seed varieties have been approved for planting in Croatia. The Law on GMO outlines the approval process, but there are no regulations that define the actual process. Thus there is a de facto ban on biotech seed plantings in Croatia with a biotech seed threshold level of 0.0%.

No biotech crops have been approved for food or feed use in Croatia, but there is a 0.9% threshold level for some GMOs in food and feed. Under special ordinance from 2004 (see section IIIa) the threshold for biotech content in food depends upon whether or not the product has previously been tested and licensed in the EU. If the product has been approved by an EU member state (a list is contained in the ordinance), it does not need to be labeled for sale on the Croatian market--provided separate tests within Croatia confirms that the product contains less than 0.9% biotech content. However, if the biotech content is above

0.9%, the product has to be labeled. The biotech threshold level drops to 0.0% for products that have not yet been approved by an EU member. The same goes for feed.

List of 0.9% threshold level allowed GMOs:

1.	GTS 40/3/2	Soybeans	Monsanto
2.	Br 176	Corn	Ciba-Geigy
3.	TOPAS 19/2	Oil rape	AgrEvo
4.	MS1/RF2	Oil rape	Plant Genetic Systems
5.	MS1/RF1	Oil rape	Plant Genetic Systems
6.	GT 73	Oil rape	Monsanto
7.	MON 810	Corn	Monsanto
8.	T 25	Corn	AgrEvo
9.	Bt 11	Corn	Novartis
10.	MON 809	Corn	Pioneer
11.	Falcon GS 40/90	Oil rape	Hoechst/AgroEvo
12.	Liberator L62	Oil rape	Hoechst/AgroEvo
13.	MS8/RF 3	Oil rape	Plant Genetic Systems
14.	1445	Cotton	Monsanto
15.	531	Cotton	Monsanto

c. Situation for with-in country biotech crop field-tests:

According to the Law on Genetically Modified Organisms, field tests of biotechnology crops are allowed. However, the regulations governing such plantings have not been issued yet.

d. Treatment of stacked events:

The Croatian legislation does not deal with or outline the treatment of stacked events to date. Future regulations may address this issue.

e. Legal framework for coexistence between biotechnology and non-biotechnology crops:

The GMO Law forbids planting of biotechnology crops in nature-protected areas, ecological areas, areas for organic agricultural production or eco tourism, and in protected areas (i.e. as defined as protection impact zones with previously enlisted zones). In addition, biotech crop plantings for reproduction are allowed only in areas that are suggested by the Ministries of Agriculture and Culture and approved by the Croatian Government in a special ordinance.

f. Labeling of packaged foods or feeds:

According to the Food Act, food and feed containing agricultural biotechnology products must have special, additional information on the label that informs consumers on all characteristics of that kind of food/feed.

g. Biosafety Protocol:

Croatia signed and ratified the Cartegena Biosafety Protocol. Officially there is no trade of biotech products, especially not with seeds. However, at present it is hard to tell whether or not the Biosafety Protocol is being applied and working in practice.

h. Biotechnology - related trade barriers:

The biggest and most important biotechnology-related trade barrier that is hurting U.S. exports is consumers' lack of acceptance for biotechnology which has resulted in restrictive basic legislation and the lack of political will to proceed with further legislation that would enable imports of biotech products.

SECTION IV

MARKETING

a. Market acceptance issues:

The average Croatian consumer has a negative opinion about food derived from biotech crops. Farmers are afraid of growing biotech plants. There is a feeling that biotechnology is something unnatural and food should be natural. The reasons for such negative opinions are various and based on values and emotions.

b. Country-Specific Studies on Acceptance of the biotechnology:

A Croatian market research agency did a study in 2005 on Public Opinion on GMOs. In this study 67% of respondents said that they wouldn't eat GMO food products under any circumstances and only 16% of respondents thought that they don't know enough about GM foodstuff.

The same research agency released the results of a study conducted in March 2004 on Croatian consumers' perception of pesticides use and biotech content in food. The results indicated that consumers view both pesticide use and biotech content in food as harmful to human health. However, excessive pesticide use was perceived as more harmful than biotech food. On average, women rated biotech food as more harmful to health than compared to men. Respondents over 60 years of age rated biotech food as more harmful than compared to younger respondents. There was an interesting trend among respondents in regards to their education levels. As

education levels increased, the harmfulness of excessive pesticide use increased while the harmfulness of biotech content in food decreased. (see GAIN report HR 5001)

SECTION V

CAPACITY BUILDING AND OUTREACH

SECTION VI
a. List of U.S. Government / USDA funded capacity building / outreach activities that have been carried out in Croatia:

2001 – Press conference held by Agricultural Counselor and Agricultural Attache on the topic of biotechnology (Sponsored by USDA)

2001/2002 – Promotional leaflets in Croatian language explaining agricultural biotechnology (Sponsored by USDA)

2002/2003 Lisa Katic, Food Industry Spokesperson – meetings with politicians, parliamentarians and government officials, roundtable discussion on biotechnology issues (sponsored by State Department)

2003 – James Maryanski, Biotechnology Coordinator for the U.S. Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition - participated and held presentation (An Approach to Assessing the Safety of Foods Derived From Plants Modified by Recombinant DNA Techniques) at the Biotechnology and Food Conference, interview with one Croatian daily news paper, embassy hosted lunch with biotech stakeholders (Sponsored by USDA)

2003 – Cochran candidate from the College of Food and Biotechnology, Scientific Assistant – Biotechnology Program (Sponsored by USDA)

2004 – Ann Marie Thro, National Program Leader for Plant Breeding and Genomics in USDA's Cooperative State Research, Education, and Extension Service – meetings with biotechnology stakeholders, press round table on biotechnology issues (Sponsored by USDA)

2005 – Dr. Peter Schmeissner, Agricultural Biotechnology Advisor, USDA/Foreign Agricultural Service (Sponsored by State Department)- meetings and lunches with biotechnology stakeholders, presentation at Agricultural College (The uses of biotechnology for providing resistance to plant diseases), radio 101 show on biotechnology issues

2005 – Cochran candidate from the College of Agronomy, Scientific Assistant – Food Safety Control Methods (Sponsored by USDA)

2006 – State Department International Visitors Program sponsored a Biotech Program for a group of biotech stakeholders from Croatia. The group was selected in cooperation with FAS.

REFERENCE MATERIAL

Gain HR 5008
Gain HR 5005
Gain HR 5004
Gain HR 5001
Gain HR/BK 4015

Gain HR 4022
Gain HR 4021
Gain HR 4016
Gain HR 4014
Gain HR 4013
Gain HR 4006
Gain HR 4002
Gain HR 3024
Gain HR 3023 (Translation of the old Food Act)
Gain HR 3019
Gain HR 5009
Gain HR 6007

Exchange rate on 6/20/2007: $1 = Kn 5.47672